Postpartum home blood pressure monitoring and lifestyle intervention in the first year after a hypertensive disorder of pregnancy: A pilot feasibility trial

Alisse Hauspurg[1], Ellen Seely[2], Janet Rich-Edwards[3], Christina Hayduchok[1], Samantha Bryan[1], Andrea Roche[2], Arun Jeyabalan[1], Esa Davis[1], Renee Hart[1], Jada Shirriel[4], and Janet Catov[1]

[1]University of Pittsburgh School of Medicine
[2]Brigham and Women's Hospital
[3]Harvard T.H. Chan School of Public Health
[4]Healthy Start, Inc

April 26, 2022

Abstract

Objective: To test the feasibility of a randomized trial of home blood pressure monitoring paired with a remote lifestyle intervention vs. home blood pressure monitoring alone vs. control in individuals with a hypertensive disorder of pregnancy in the first year postpartum. Design: Single-blinded randomized clinical trial Setting: Two tertiary hospitals and a community organization Population: Overweight and obese individuals with a hypertensive disorder of pregnancy and without pre-pregnancy hypertension or diabetes. Methods: We assessed the feasibility of recruitment and retention of 150 participants to study completion at one-year postpartum with randomization 1:1:1 into each arm. Secondary aims were to test effects of the interventions on weight, blood pressure and self-efficacy. Results: Over 23 months, we enrolled 148 of 400 eligible, screened individuals (37%); 28% Black or Other race, and mean pre-pregnancy BMI of 33.4±6.7 kg/m2. In total, 129 (87%) participants completed the one-year postpartum study visit. Overall, 22% of participants developed stage 2 hypertension [[?]140/90 mmHg or on anti-hypertensive medications] by one-year postpartum. Individuals in the lifestyle intervention arm had a greater, non-significant decrease in mean arterial pressure (MAP) compared to individuals in the HBPM alone and control arm [mean change in MAP (95%CI) -3.7(-6.5, -0.9), -0.5(-1.5, 2.6), -1.0(-4.1, 2.2) mmHg], respectively. There were no differences in weight or self-efficacy by study arms. Conclusion: In this pilot, randomized trial, we demonstrate feasibility of HBPM paired with a lifestyle intervention in the first year postpartum. We detected high rates of ongoing hypertension emphasizing the need for effective interventions in this population.

INTRODUCTION

Hypertensive disorders of pregnancy (HDP), including gestational hypertension and preeclampsia complicate 8-10% of pregnancies in the United States. The association of HDP with later-life cardiovascular disease (CVD) is well-established and has been replicated in diverse populations across multiple studies.(1–4) Recent data suggest 30-40% of previously normotensive individuals progress to chronic hypertension in the first year following HDP, which is likely a key contributor to CVD risk.(5,6) In overweight and obese individuals, that risk is further amplified, with prior studies demonstrating that over 50% have sustained hypertension at one-year postpartum.(7) Despite this, few interventions have been studied to mitigate risk in this population.(8)

Traditional in-person interventions, such as regular appointments and counseling from a primary care doctor or nutritionist may promote lifestyle changes in the general adult population, but this has not been as

successful for primary prevention in a postpartum population, likely due to competing demands and time constraints.(9–11) However, following a pregnancy complication, the immediate postpartum period is a time when individuals may be particularly motivated to improve their health, both before the next pregnancy and long-term.(12,13) Self-monitoring via home blood pressure monitoring as a tool to lower blood pressure is supported by robust evidence in the general adult population. When self-monitoring of home blood pressure is combined with additional support (education, counseling, individualized feedback, patient navigator), further lowering of blood pressure is achieved in a general hypertensive population.(14) Internet-based lifestyle interventions implemented in the immediate postpartum period promote weight loss in individuals with a history of gestational diabetes and show high engagement and retention postpartum (15,16) but these are not well-studied in individuals after HDP. Prior postpartum intervention studies have had high attrition rates, which suggested that postpartum individuals may not be willing to participate in intervention studies due to the competing demands of the immediate postpartum period, highlighting the need for a feasibility study prior to proceeding with a large-scale randomized trial.(17,18)

The initial Heart Health 4 Moms study developed a remote lifestyle intervention that was internet-based and mobile-device compatible which demonstrated improvement in knowledge of CVD risk and self-efficacy to achieve a healthy diet and decreased physical inactivity among predominantly white and highly educated postpartum individuals within the first five years following a pregnancy complicated by preeclampsia.(8) Our primary aim in this three-arm trial was to examine the feasibility of conducting a randomized controlled trial comparing home blood pressure monitoring plus the internet-based lifestyle intervention, Heart Health 4 New Moms (HH4NM) compared to home blood pressure monitoring alone compared to a control arm, in a racially and socioeconomically diverse sample of overweight and obese individuals with a hypertensive disorder of pregnancy in the first year postpartum. Our secondary aims were to test whether the interventions (HH4NM +HBPM or HPBM alone) would lower weight and blood pressure compared to controls.

METHODS

Study recruitment

Between June 2019 and May 2021, we recruited adult postpartum individuals who had delivered within the past six months at one of two tertiary care hospitals within a single hospital system (Magee-Womens Hospital in Pittsburgh or Magee-Womens Hospital in Erie) or through our partner community organization, Healthy Start, Inc. Healthy Start, Inc. is a community-based organization that seeks to improve maternal and child health, reduce poor birth outcomes and infant mortality as well as eliminate perinatal health disparities in the Pittsburgh community. Individuals were eligible if they had a pre-pregnancy body mass index (BMI) in the overweight or obese range ([?]25 kg/m^2). If pre-pregnancy weight was unknown, we used a weight measured clinically in the first trimester of pregnancy. We enrolled participants between 6 weeks and 6 months postpartum if they had a pregnancy complicated by gestational hypertension or preeclampsia according to American College of Obstetricians and Gynecologists' (ACOG) criteria (19), were [?]18 years of age, English-speaking and had access to a device with internet connectivity. Individuals were excluded if they had a pre-pregnancy history of diabetes, chronic hypertension or were noted to have elevated blood pressure ([?]140 / 90 mmHg) before 20 weeks gestation, known coronary artery disease, underlying chronic kidney disease pre-pregnancy, autoimmune disease requiring medications, multifetal gestation, stillbirth or neonatal death or were pregnant at the time of enrollment. Inclusion criteria were evaluated through a phone or in-person screen and medical record review by research staff. Participants who became pregnant during the intervention were asked to discontinue the intervention and were withdrawn from the study.

Participants who met inclusion criteria were either identified at the time of delivery by the research study staff or in the postpartum period during home visits by Community Health Workers at Health Start, Inc. Eligible participants were identified by medical record review by the study physician (AH) and pregnancy outcomes were adjudicated by two independent physicians (AH& AJ) using ACOG criteria for diagnosis of gestational hypertension and preeclampsia.(19) Before March 2020, eligible participants were recruited during their postpartum hospitalization. After March 2020, due to the Covid-19 pandemic and restrictions on in-person research activities at our institution, all recruitment and study procedures were conducted

remotely via phone and video visits. Individuals who were eligible following medical record review were contacted either in person or via a recruitment letter (after March 2020). All participants provided written informed consent.

Control arm intervention

The control arm received access to the Heart Health 4 New Moms control website, which included publicly available information regarding cardiovascular risk associated with preeclampsia and gestational hypertension and lifestyle recommendations to prevent cardiovascular disease from the American Heart Association and the Preeclampsia Foundation.

HBPM arm intervention

Participants in this arm received resources on the HH4NM website available to the control arm plus a blood pressure monitor (iHealth, Wireless Blood Pressure Monitor BP5). Arm circumference was measured at the initial study visit and individuals received an appropriately sized cuff. Participants received instruction from study staff on home measurement of blood pressure and were asked to measure blood pressure daily for one week out of each month, two measures in the morning and two measures in the evening.(20) Participants were instructed on proper measurement technique, including measuring in the seated position after five minutes at rest. We used automated text messaging for reminders. Individuals received summative information through the iHealth application, as well as monthly summaries from study staff outlining the number of measures provided, mean blood pressure values and their comparisons to prior months.

HBPM + lifestyle intervention

Participants in this arm received all interventions outlined above for the HPBM arm, plus an electronic scale (iHealth Lite Wireless Scale, model HS4) plus access to the HH4NM lifestyle program website, which includes: audiovisual modules on healthy eating, modeled on the Dietary Approaches to Stop Hypertension (DASH) diet, increasing physical activity and identifying barriers to adopting a healthy lifestyle.(21) Participants received online badges for completing modules and setting goals through action plans and received personalized lifestyle coaching from a registered dietician (ATR). Coaching was provided through six scheduled calls and three scheduled emails, with interim communication as initiated by participants. Interested participants were also enrolled in a study-specific Facebook group to allow for peer support through communication with each other and the lifestyle coach. Finally, participants received access to a toolbox of additional resources, including meal plans, recipes and instructional exercise videos that could be done with an infant.

Randomization and Blinding

Once the questionnaire and initial measurements were completed, participants were randomized to either a control arm, HBPM alone or HBPM plus HH4NM intervention in a 1:1:1 allocation. We utilized a block randomization schema with block sizes of six generated by a blinded statistician using the procedure PLAN in the statistical software package SAS (SAS Institute, Inc., Cary, NC). Study staff and study physicians and investigators interacting with prospective participants during recruitment were blinded to which arm a participant would be randomized. Study staff, who conducted the study visits and instructed participants on study protocols were unblinded at the time of randomization. Study physicians, investigators and the statistician remained blinded until completion of all study visits.

Follow up and assessment of outcomes

All participants underwent two assessments: baseline (pre-randomization; 6 weeks to 6 months postpartum) and at study completion (8-12 months postpartum) after completing at least 6 months in the study. Enrolled participants were emailed a link to a questionnaire, which was completed before or at the time of the first two study visits. Before March 2020, all participants underwent a study visit either in the Magee-Womens Clinical and Translational Research Center (CTRC) or via home research study visits, per participant preference. After March 2020 (due to COVID pandemic restrictions), study visits were conducted remotely. At the time of each assessment, participants completed online questionnaires and measured blood pressure at rest, while

sitting for at least 5 minutes. Blood pressure measures were either collected by study staff (pre-pandemic) or observed by study staff virtually using a secured Zoom room and were repeated three times. Blood pressures were measured using either an iHealth, Wireless Blood Pressure Monitor BP5 or an A&D UA-651 (A&D Medical; San Jose, California) automatic upper arm blood pressure monitor, both validated by Dabl Educational Trust and the British Society for Hypertension for use in postpartum individuals. The mean of the three measures was used in analysis. Mean arterial pressure was calculated with the formula [systolic BP+(2*diastolic BP)/3]. Weight measures were collected either by study staff during an in-person visit, pre-pandemic, or were directly observed during a remote study visit using a study-provided iHealth or Etekcity Digital Body Weight scale. Individuals were weighed in light clothing without shoes at the time of the study visit for both in-person and remote study visits. Participants in all three arms received monthly emails thanking them for their ongoing participation.

The primary objective of this pilot study was to evaluate the feasibility of a randomized trial of home blood pressure monitoring vs home blood pressure monitoring plus a lifestyle intervention vs control in the first year postpartum. Feasibility of recruitment and retention (proportion and 95% CI) was assessed to study completion. Our predefined measures for feasibility success included randomization of 8-10 participants per month and retention of [?]80% of participants to one-year postpartum, with a target to complete all recruitment at the primary site during an 18-month period and recruitment at both sites over a 24-month period. Our primary efficacy outcome was participant weight at the second study visit, which was chosen as a patient-centered outcome for postpartum individuals. Secondary outcomes included: 1) blood pressure and change in blood pressure parameters across the study; 2) participant BMI and weight change across the study, 3) adherence to intervention, 4) self-efficacy 5) prevalence of stage 1 and 2 HTN, 6) use of anti-hypertensive medications at study completion and 7) prevalence of lifestyle behaviors. Stage 1 and stage 2 hypertension were defined using the 2017 American College of Cardiology / American Heart Association guidelines - stage 1 hypertension: systolic BP 130-139 mmHg or diastolic BP 80-89 mmHg and stage 2 hypertension: systolic BP [?]140 mmHg, diastolic BP [?]90 mmHg or requiring anti-hypertensive medications.(22)

Self-efficacy towards achieving a healthy diet and level of physical activity was assessed using an adapted version of the validated Sallis Eating Habits Confidence Survey and Exercise Confidence Survey scales.(23) We used the Pregnancy Physical Activity Questionnaire to assess physical activity (type, duration, and frequency) and inactivity (sedentary behavior), which is a validated questionnaire for women that includes activities related to caring for young children. Time spent in each activity weekly is multiplied by its intensity to yield the average weekly energy expenditure.(24) Sodium intake was quantified using an adapted version of the validated Sodium Screener developed by Block (©NutritionQuest 2011) to assess sodium intake as a continuous variable. The Sodium Screener includes foods contributing to 80% of sodium intake in which there are five frequency response categories—from rarely or never (assigned a value of 0) to every day (assigned a value of 4). The cumulative score ranges from 0 to 67, with higher scores signifying higher sodium intakes. For women, sodium intake less than 2300 mg per day corresponds to scores between 18-24.(25)

A core outcome set (COS) does not exist for this research subject area, thus a COS was not used when designing the trial.

Study sites

As noted above, participants were enrolled from one of two hospital sites or through Healthy Start, Inc. The initial trial protocol aimed to enroll participants from a single, urban site. After the trial and intervention were converted to be delivered fully remotely as a result of the COVID-19 pandemic, the opportunity arose to enroll participants from a second site (with a more rural population). As the primary intention of this trial was feasibility, we opted to enroll 30 additional participants from this second site within our hospital system to assess the feasibility of conducting this research at more than one study location.

Patient involvement

Preeclampsia survivors affiliated with the Preeclampsia Foundation were involved in the design of all intervention content and website layouts for the HH4NM intervention and adapted with key stakeholders at

Healthy Start, Inc. Study participants were involved in the review and interpretation of results following study completion.

Statistical analysis

We followed the intention-to-treat principle and included all randomized participants. The target sample size for enrollment was 150 participants to establish feasibility and given cost constraints, with 120 from the primary site and 30 from the second site (as described above), for a target of 50 in each of the three arms, following published guidelines for feasibility studies.(26) A formal sample size calculation was not performed as the primary objective of this study was to assess feasibility. All analyses were performed in Stata IC 16 software package (StataCorp LP, College Station, TX). Continuous variables are reported as means with 95% CI or SD (or medians with interquartile ranges [IQR]) and categorical variables are reported as count and proportions. Differences between arms were reported with 95% confidence intervals (95% CI). An interim analysis was performed following completion of the study at the primary study site as was initially outlined in the study protocol prior to adding the second study site. To evaluate the effect of the interventions (HH4NM + HBPM vs. HBPM alone vs. control), we compared continuous variables between the three arms at the second study visit (follow-up) using standard ANOVA. We also compared the change in outcomes of interest between arms using ANOVA. At the same time points, categorical data were compared between arms using logistic regression and χ^2 test. In sub-group analyses, we evaluated the feasibility and effects of the interventions by race, pre-pregnancy BMI category, and type of hypertensive disorder of pregnancy. We used all data available from randomized participants without replacement of missing data.

Institutional approval

The protocol was approved by the Institutional Review Board of the University of Pittsburgh (STUDY18080007) and all participants provided written informed consent. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Pittsburgh. The study protocol was registered with Clinicaltrials.gov (NCT03749746) before any enrollment of participants. A data safety and monitoring committee provided study oversight. There were no adverse events reported.

RESULTS

Enrollment feasibility

Between January 2019 and March 2021, 613 individuals were screened for eligibility (Figure 1). Nine individuals were ineligible because they did not meet study criteria, recruitment closed before screening was done on 204 participants. Of the remaining individuals (n=400), 166 declined to participate and 86 were lost to follow up during the recruitment process. We enrolled 148 of 400 eligible, screened individuals (recruitment 37%; 95%CI 32.2%, 41.9%) over a 23-month period (June 2019-May 2021). Demographic characteristics were overall similar between enrolled versus unenrolled participants (Table S1).

Baseline characteristics

Baseline characteristics of the 148 study participants are summarized in Table 1. Participants were on average 30.8± 5.1 years of age, 28% self-identified as Black or Other race with a mean pre-pregnancy BMI in the obese range, 33.4±6.7 kg/m^2 and 37% were insured through public health insurance. Participants delivered at 37.2 ± 3.1 weeks gestation (range 26.6-41.3 weeks) and mean infant birthweight was 2969 ± 786 grams. Mean gestational weight gain was 31.9 ± 18.7 pounds. The majority of participants had a diagnosis of preeclampsia (n=93; 63%) with 61% (n=57) of these having severe features and 24% (n=36) delivered preterm (<37 weeks gestation). Additionally, 17 (12%) individuals had pregnancies complicated by gestational diabetes.

Participants were enrolled at a mean of 10.5±6.1 weeks postpartum, with 101/148 (68%) participants enrolled in the first three months postpartum. Mean MAP at enrollment was 96±11mmHg (Table 2). Mean blood pressure was 124±14 mmHg systolic and 82±10mmHg diastolic. Thirty-seven (25%) participants were on anti-hypertensive medications at the time of enrollment, with a total of 99 (67%) meeting criteria for stage

1 hypertension or greater at enrollment. Mean BMI at enrollment was 33.9±6.3 kg/m^2. At enrollment, 83 (56%) participants reported that they were feeding their baby breastmilk (expressed or direct breastfeeding any amount).

Retention and adherence

129 of 148 participants completed the second study visit (87.1% retention; 95%CI 80.6%, 91.6%) at a mean of 10.9 ± 2.1 months postpartum, with a mean participation time of 8.5 ± 2.0 months, which did not differ by study arm (p=0.8). Four (3%) participants became pregnant before study completion. Retention ranged from 76% in the HH4NM +HBPM arm to 86% in HBPM alone arm to 100% in the control arm and did not differ by self-reported race, type of hypertensive disorder, pre-pregnancy BMI or study site. No difference was seen in the mean number of blood pressures reported per month between the HBPM arm (mean 11.2± 9.9) and the HH4NM +HBPM arm (mean 10.9± 8.6; p=0.9). Participants in the HH4NM +HBPM arm had a mean of 4.9 ± 3.3 phone contacts with the lifestyle coach and 45 of 51 individuals (88%) had at least one contact with the lifestyle coach. During the study period, 44 of 51 participants (86%) accessed the study website at least once.

Effect of intervention weight and blood pressure

There were no statistical differences in weight, BMI at follow up visit or weight change from enrollment by study arm (Table 3). Overall, participants retained a mean of 9.5 ± 18.5 pounds above their pre-pregnancy weight. Thirty-eight (29%) participants were back to their pre-pregnancy weight by study completion. HBPM plus HH4NM intervention led to a greater but not statistically significant decrease in systolic, diastolic and mean arterial pressure (MAP) between the two study visits (Table 3) when compared to HBPM alone and control [mean change in MAP (95%CI) -3.7(-6.5, -0.9), -0.4(-6.6, 1.0), -1.0(-4.1, 2.2) mmHg], respectively. Differences in SBP and DBP were similar. Overall, 75 (58%) participants met criteria for stage 1 hypertension or greater and 28 (22%) met criteria for stage 2 hypertension with 13 (10%) participants on anti-hypertensive medication at one-year postpartum with no difference by study arm. Because of the small sample size, the arms appeared to be less balanced by race and type of HDP. Post-hoc, we examined whether these factors may have influenced our findings. Adjustment for type of hypertensive disorder and race did not change our estimates.

Effect of intervention on activity and diet

Self-efficacy for healthy eating and physical activity levels was high across all study arms at baseline (mean 4.27; 95%CI 4.16, 4.39 for healthy eating and mean 3.76; 95%CI 3.62, 3.89 for activity). There was no difference in self-efficacy for healthy eating and physical activity levels at enrollment and follow up by study arm and no difference in the change in self-efficacy towards healthy eating and activity across the study. Participants in all three arms had a decrease in physical inactivity time and increase in physical activity across the study period with no difference by arm. Mean score on the Block Sodium Screener increased during the study period in the control and HBPM alone arm by 2.2±13.0, but decreased in the HH4NM + HBPM arm; -3.9 ± 12.2, p=0.02 in post-hoc analysis of HH4NM + HBPM vs. other arms (HBPM alone and control).

DISCUSSION

Main findings

We demonstrate feasibility and high retention in a randomized trial of postpartum home blood pressure monitoring plus a lifestyle intervention among a diverse sample of overweight and obese individuals with HDP. Importantly, while our study is not powered to show a statistical difference in efficacy, we note that home blood pressure monitoring and home blood pressure monitoring plus our lifestyle intervention arms had lower mean arterial blood pressure compared to controls at one-year postpartum and we detected statistically significant decreases in sodium consumption associated with the full intervention. We also demonstrate a high proportion of participants with ongoing hypertension at one-year postpartum, with over half meeting criteria for stage 1 hypertension, over 20% with stage 2 hypertension and 10% of participants still requiring

anti-hypertensive agents. We showed no statistical difference in weight change across study arms, suggesting that any changes in blood pressure were not secondary to weight loss in the intervention arms. Particularly relevant in this population of overweight and obese participants is the significant weight retention at one-year postpartum, with less than 30% of individuals returning to their pre-pregnancy weight by study completion.

Interpretation

Hypertensive disorders of pregnancy are associated with increased CVD risk across multiple studies in diverse populations.(1,2) There is compelling evidence that hypertension accounts for much of the CVD risk following a hypertensive disorder of pregnancy, yet few interventions have been studied to reduce progression to hypertension after a hypertensive disorder of pregnancy.(27–29) Our previous work has demonstrated that overweight and obese individuals have high rates of ongoing hypertension at one-year postpartum and that overall individuals may be particularly motivated to lower blood pressure following a hypertensive disorder of pregnancy.(7)

Prior postpartum intervention studies have had high attrition rates, which suggested that postpartum individuals may not be willing to participate in intervention studies or engage in follow up care due to the competing demands of the immediate postpartum period.(17,18) We enrolled participants within the first six months postpartum and retained almost 90% to one-year. Our study design was adapted to meet institutional regulatory requirements in the setting of the COVID-19 pandemic, and a remote approach to recruitment and study visits may in fact be well suited to this population. Before transitioning to a remote approach, we offered individuals two options for the first study visit, in-office study visit or a home visit. Among these early participants, 58% (n=26) opted for a home study visit, highlighting the potential utility and desirability of this approach in the postpartum period as well as the synergy of community partnering. Our overall enrollment rates are in line with other studies of remote lifestyle interventions for weight loss postpartum, but future work is warranted to understand barriers to broaden enrollment of eligible participants. (30,31) Of the individuals who declined to participate, reasons cited included that being too busy or having the perception that their HDP "wasn't that bad" so they didn't need an intervention. Future work should focus on additional education and risk counseling in the postpartum period to enhance understanding of future CV risk following a HDP. Additionally, consideration of enhanced recruitment methods such as the use of social media platforms or using technology to identify and recruit participants and the use of community-based enrollment (e.g Women, Infants, Children [WIC] or doula community programs) or integration with a clinical postpartum visit may improve uptake of our intervention.

The parent Heart Health 4 Moms trial demonstrated improvement in knowledge of CVD risk and self-efficacy to achieve a healthy diet and decrease physical inactivity among predominantly white and highly educated individuals within the first five years following a pregnancy complicated by preeclampsia(8). The parent trial excluded individuals with BP [?]140/90 mmHg, who were on anti-hypertensive agents or had a BMI [?]40 kg/m^2. Compared to the initial trial, by design, we enrolled a more diverse, higher-risk population, with 25% on anti-hypertensive agents and 25% with a BP [?]140/90 mmHg at enrollment. Importantly, we note that the majority of participants were able to come off anti-hypertensive agents during the trial period.

Recent work has demonstrated that pharmaceutical interventions in the immediate postpartum period may improve blood pressure and cardiovascular function in the first year postpartum.(32,33) The SNAP-HT trial randomized postpartum individuals who were on anti-hypertensive agents following a hypertensive disorder of pregnancy to usual care with in-office blood pressure assessments versus home blood pressure monitoring plus management with systematic titration of anti-hypertensive medications in the postpartum period. Cairns and colleagues found that this approach was feasible and resulted in improved diastolic blood pressure with a lowering of 4.5mmHg seen in the intervention group up to 6 months postpartum.(33) Similarly, individuals with preterm preeclampsia randomized to postpartum enalapril have improved diastolic function and left ventricular remodeling at 6 months postpartum when compared to individuals randomized to placebo.(32) These studies suggest that the immediate postpartum period may be particularly important for cardiovascular remodeling and that interventions in this period may improve both short and long-term cardiovascular risk.

Despite promising data in the non-pregnant population, few studies have investigated self-monitoring of BP combined with additional support. Our study found a modest lowering of blood pressure in the intervention arms. Given the evidence that modest BP elevations among young adults (<40 years) are linked to significantly higher risk for subsequent CV disease events when compared with those with normal BP, modest BP improvements may be important.(34) Although our findings are promising, the ongoing high rates of hypertension and need for anti-hypertensive medication suggest the potential need for interventions beyond home monitoring and lifestyle support in a proportion of this population. Thus, postpartum monitoring may help stratify groups for lifestyle versus more intensive follow-up to improve BP control. Our findings support the need for larger studies with longer follow up postpartum. One major limitation to interventions beyond the immediate postpartum period is access to care. For individuals with public health insurance, in many states within the United States, Medicaid coverage lasts only through sixty days postpartum. The high rates of ongoing hypertension in our population highlight the critical need for Medicaid expansion to at least one year postpartum and the importance of successful transitions of care postpartum from the obstetrician to the primary care physician.

We saw no improvement in self-efficacy towards healthy diet and activity or levels of physical activity and inactivity in the HH4NM + HBPM arm, perhaps related to the high levels of self-efficacy at baseline. We also saw no significant effect of our intervention on weight change. Prior studies have shown that diet alone and diet paired with exercise after delivery lead to greater weight loss compared to usual care in a general postpartum population, not specifically in overweight or obese individuals following a hypertensive disorder of pregnancy. A meta-analysis of 7 trials demonstrated that diet combined with exercise was significantly associated with postpartum weight loss with a mean difference of 1.93 kg.(35) The dietary counseling in our intervention was centered around implementing a DASH diet, as such, we note that total daily sodium consumption, as measured by the Block Sodium Screener decreased in the HH4NM + HBPM arm compared to the other two arms. Consistent with a non-pregnant and postpartum population, we found that higher sodium intake as assessed with the Sodium Screener was associated with higher blood pressure and that individuals with persistent hypertension at the conclusion of the study reported higher sodium intake.(36–38) These findings support the possibility of lower sodium intake leading to a greater reduction in blood pressure in the intervention arm of our study and warrant further investigation with more robust assessments such as urinary sodium excretion. This could be relevant, as a recent study in individuals approximately five years postpartum found that those with a history of preeclampsia have an impaired ability to adapt their arterial stiffness (as assessed by pulse wave velocity) in response to a change in sodium intake when compared to those with a history of normal pregnancy.(39)

Strengths and limitations

Given the pilot nature of this study, we were not powered to detect statistically significant changes in weight or blood pressure associated with our intervention. As such, our study is limited by the small sample size, and an overall enrollment of 37% of eligible, screened individuals, limiting its generalizability. Additionally, those who enrolled were more likely to have a pregnancy complicated by preeclampsia with severe features compared to those who did not enroll. Eligibility for the study required individuals to have a device with internet access, which may have limited the economic diversity of individuals eligible to participate, although we note that no one who declined to participate cited lack of access to internet as a reason at our primary site, but two individuals of the 102 screened (2%) at our secondary site declined to participate due to unreliable phone / internet service and lack of access to an appropriate device. These issues related to lack of access to broadband internet likely disproportionately impact rural populations and limit the generalizability of our intervention. In the future, engagement with such an intervention may be increased with the use of an application (app), simple text message reporting of blood pressures or with integration into clinical care. Much like the parent HH4M study, the control arm likely received more information than most receive in "usual care," as prior studies have demonstrated that most clinicians and patients are either unaware or do not communicate the increased risk of CVD to postpartum individuals with a history of hypertensive disorder.(12,40) Our physical activity assessments were based on participant recall and subjective report, rather than objectively obtained data, such as using actigraphy, and may have been too insensitive to

measure modest change. Given the global COVID-19 pandemic, we chose to pivot our approach to remote recruitment and study visits and add a second study site, with a change in our protocol after recruitment of approximately one-third of our planned sample size. In addition, we were unable to assess if there may have been COVID-related impacts on our findings.

Conclusion

Our results demonstrated high engagement and retention of overweight and obese postpartum individuals in a randomized control trial in the first year following a hypertensive disorder of pregnancy. We found that home blood pressure monitoring (HBPM) in combination with a lifestyle intervention showed a trend of lower blood pressure and significantly greater decrease in sodium intake in this high-risk population. Our findings warrant confirmation with a larger trial powered to show differences in blood pressure and weight outcomes. We detected high rates of ongoing hypertension and significant weight retention postpartum, suggesting that interventions beyond HBPM and lifestyle coaching may be needed to lower blood pressure and support weight loss.

FUNDING

This work was supported by the Jewish Healthcare Foundation, Amy Roberts Health Promotion Award, by funds from Magee-Womens Research Institute's Erie initiative, The Erie Community Foundation and Hamot Health Foundation and by NIH/ORWH Building Interdisciplinary Research Careers in Women's Health (BIRCWH) NIH K12HD043441 to AH. Dr Esa Davis is a member of the US Preventive Services Task Force (USPSTF); this article does not necessarily represent the views and polices of the USPSTF.

ETHICS APPROVAL

The protocol was approved by the Institutional Review Board of the University of Pittsburgh (STUDY18080007) on January 9, 2019 and all participants provided written informed consent.

CONTRIBUTION TO AUTHORSHIP

AH: Substantial contributions to the conception, design, acquisition, analysis and interpretation of data. Drafting the manuscript and manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

EWS: Substantial contributions to the design, analysis and interpretation of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

JRE: Substantial contributions to the design, analysis and interpretation of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

CH: Substantial contributions to the design, and acquisition of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

SB: Substantial contributions to the acquisition, analysis and interpretation of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

ATR: Substantial contributions to the conception, design, and acquisition of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

AJ: Substantial contributions to the design, analysis and interpretation of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

ED: Substantial contributions to the analysis and interpretation of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

RH: Substantial contributions to the acquisition of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

JS: Substantial contributions to the conception, design, and acquisition of data. Substantial contribution to manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

JC: Substantial contributions to the conception, design, acquisition, analysis and interpretation of data. Drafting the manuscript and manuscript revisions. Final approval of the work and agreement to be accountable for all aspects of the work.

DISCLOSURE OF INTERESTS

Dr Esa Davis is a member of the US Preventive Services Task Force (USPSTF); this article does not necessarily represent the views and polices of the USPSTF.

REFERENCES

1. Wu P, Haththotuwa R, Kwok CS, Babu A, Kotronias RA, Rushton C, et al. Preeclampsia and Future Cardiovascular Health: A Systematic Review and Meta-Analysis. Circ Cardiovasc Qual Outcomes. 2017 Feb 22;10(2).

2. Bellamy L, Casas J-P, Hingorani AD, Williams DJ. Pre-eclampsia and risk of cardiovascular disease and cancer in later life: systematic review and meta-analysis. BMJ. 2007 Nov 10;335(7627):974.

3. McDonald SD, Malinowski A, Zhou Q, Yusuf S, Devereaux PJ. Cardiovascular sequelae of preeclampsia/eclampsia: a systematic review and meta-analyses. Am Heart J. 2008 Nov;156(5):918–930.

4. Hauspurg A, Ying W, Hubel CA, Michos ED, Ouyang P. Adverse pregnancy outcomes and future maternal cardiovascular disease. Clin Cardiol. 2018 Feb 15;41(2):239–246.

5. Benschop L, Duvekot JJ, Versmissen J, van Broekhoven V, Steegers EAP, Roeters van Lennep JE. Blood pressure profile 1 year after severe preeclampsia. Hypertension. 2018 Mar;71(3):491–498.

6. Smith GN, Pudwell J, Saade GR. Impact of the new american hypertension guidelines on the prevalence of postpartum hypertension. Am J Perinatol. 2019;36(4):440–442.

7. Hauspurg A, Countouris ME, Jeyabalan A, Hubel CA, Roberts JM, Schwarz EB, et al. Risk of hypertension and abnormal biomarkers in the first year postpartum associated with hypertensive disorders of pregnancy among overweight and obese women. Pregnancy hypertension. 2019 Jan;15:1–6.

8. Rich-Edwards JW, Stuart JJ, Skurnik G, Roche AT, Tsigas E, Fitzmaurice GM, et al. Randomized Trial to Reduce Cardiovascular Risk in Women with Recent Preeclampsia. J Womens Health (Larchmt). 2019 Jun 19;28(11):1493–1504.

9. Sarwer DB, Allison KC, Gibbons LM, Markowitz JT, Nelson DB. Pregnancy and obesity: a review and agenda for future research. J Womens Health (Larchmt). 2006 Aug;15(6):720–733.

10. Ostbye T, Krause KM, Lovelady CA, Morey MC, Bastian LA, Peterson BL, et al. Active Mothers Postpartum: a randomized controlled weight-loss intervention trial. Am J Prev Med. 2009 Sep;37(3):173–180.

11. Nicklas JM, Zera CA, Seely EW, Abdul-Rahim ZS, Rudloff ND, Levkoff SE. Identifying postpartum intervention approaches to prevent type 2 diabetes in women with a history of gestational diabetes. BMC Pregnancy Childbirth. 2011 Mar 24;11:23.

12. Skurnik G, Roche AT, Stuart JJ, Rich-Edwards J, Tsigas E, Levkoff SE, et al. Improving the postpartum care of women with a recent history of preeclampsia: a focus group study. Hypertens Pregnancy. 2016 Aug;35(3):371–381.

13. Spaan J, Peeters L, Spaanderman M, Brown M. Cardiovascular risk management after a hypertensive disorder of pregnancy. Hypertension. 2012 Dec;60(6):1368–1373.

14. Uhlig K, Patel K, Ip S, Kitsios GD, Balk EM. Self-measured blood pressure monitoring in the management of hypertension: a systematic review and meta-analysis. Ann Intern Med. 2013 Aug 6;159(3):185–194.

15. Nicklas JM, Zera CA, England LJ, Rosner BA, Horton E, Levkoff SE, et al. A web-based lifestyle intervention for women with recent gestational diabetes mellitus: a randomized controlled trial. Obstet Gynecol. 2014 Sep;124(3):563–570.

16. Ferrara A, Hedderson MM, Brown SD, Albright CL, Ehrlich SF, Tsai A-L, et al. The comparative effectiveness of diabetes prevention strategies to reduce postpartum weight retention in women with gestational diabetes mellitus: the gestational diabetes' effects on moms (GEM) cluster randomized controlled trial. Diabetes Care. 2016 Jan;39(1):65–74.

17. Lewey J, Levine LD, Yang L, Triebwasser JE, Groeneveld PW. Patterns of Postpartum Ambulatory Care Follow-up Care Among Women With Hypertensive Disorders of Pregnancy. J Am Heart Assoc. 2020 Sep;9(17):e016357.

18. Levine LD, Nkonde-Price C, Limaye M, Srinivas SK. Factors associated with postpartum follow-up and persistent hypertension among women with severe preeclampsia. J Perinatol. 2016 Sep 1;36(12):1079–1082.

19. ACOG practice bulletin no. 202: gestational hypertension and preeclampsia. Obstet Gynecol. 2019 Jan;133(1):1.

20. Pickering TG, Miller NH, Ogedegbe G, Krakoff LR, Artinian NT, Goff D, et al. Call to action on use and reimbursement for home blood pressure monitoring: executive summary: a joint scientific statement from the American Heart Association, American Society Of Hypertension, and Preventive Cardiovascular Nurses Association. Hypertension. 2008 Jul;52(1):1–9.

21. Sacks FM, Svetkey LP, Vollmer WM, Appel LJ, Bray GA, Harsha D, et al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group. N Engl J Med. 2001 Jan 4;344(1):3–10.

22. Whelton PK, Carey RM, Aronow WS, Casey DE, Collins KJ, Dennison Himmelfarb C, et al. 2017 acc/aha/aapa/abc/acpm/ags/apha/ash/aspc/nma/pcna guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: executive summary: A report of the american college of cardiology/american heart association task force on clinical practice guidelines. Hypertension. 2018 Jun;71(6):1269–1324.

23. Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR. The development of scales to measure social support for diet and exercise behaviors. Prev Med. 1987 Nov;16(6):825–836.

24. Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and validation of a Pregnancy Physical Activity Questionnaire. Med Sci Sports Exerc. 2004 Oct;36(10):1750–1760.

25. Norris J, Block G, Block T. Development of a brief screening tool for sodium intake. 2012 Oct 30;

26. Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. Trials. 2014 Jul 3;15:264.

27. Romundstad PR, Magnussen EB, Smith GD, Vatten LJ. Hypertension in pregnancy and later cardiovascular risk: common antecedents? Circulation. 2010 Aug 10;122(6):579–584.

28. Powe CE, Levine RJ, Karumanchi SA. Preeclampsia, a disease of the maternal endothelium: the role of antiangiogenic factors and implications for later cardiovascular disease. Circulation. 2011 Jun 21;123(24):2856–2869.

29. Haug EB, Horn J, Markovitz AR, Fraser A, Klykken B, Dalen H, et al. Association of Conventional Cardiovascular Risk Factors With Cardiovascular Disease After Hypertensive Disorders of Pregnancy: Analysis of the Nord-Trondelag Health Study. JAMA Cardiol. 2019 Jul 1;4(7):628–635.

30. Phelan S, Hagobian T, Brannen A, Hatley KE, Schaffner A, Munoz-Christian K, et al. Effect of an Internet-Based Program on Weight Loss for Low-Income Postpartum Women: A Randomized Clinical Trial. JAMA. 2017 Jun 20;317(23):2381–2391.

31. Holmes VA, Draffin CR, Patterson CC, Francis L, Irwin J, McConnell M, et al. Postnatal lifestyle intervention for overweight women with previous gestational diabetes: A randomized controlled trial. J Clin Endocrinol Metab. 2018 Jul 1;103(7):2478–2487.

32. Ormesher L, Higson S, Luckie M, Roberts SA, Glossop H, Trafford A, et al. Postnatal Enalapril to Improve Cardiovascular Function Following Preterm Preeclampsia (PICk-UP):: A Randomized Double-Blind Placebo-Controlled Feasibility Trial. Hypertension. 2020 Dec;76(6):1828–1837.

33. Cairns AE, Tucker KL, Leeson P, Mackillop LH, Santos M, Velardo C, et al. Self-Management of Postnatal Hypertension: The SNAP-HT Trial. Hypertension. 2018 Aug;72(2):425–432.

34. Yano Y, Reis JP, Colangelo LA, Shimbo D, Viera AJ, Allen NB, et al. Association of blood pressure classification in young adults using the 2017 american college of cardiology/american heart association blood pressure guideline with cardiovascular events later in life. JAMA. 2018 Nov 6;320(17):1774–1782.

35. Amorim Adegboye AR, Linne YM. Diet or exercise, or both, for weight reduction in women after childbirth. Cochrane Database Syst Rev. 2013 Jul 23;(7):CD005627.

36. Countouris ME, Schwarz EB, Rossiter BC, Althouse AD, Berlacher KL, Jeyabalan A, et al. Effects of lactation on postpartum blood pressure among women with gestational hypertension and preeclampsia. Am J Obstet Gynecol. 2016 Aug;215(2):241.e1–8.

37. Juraschek SP, Miller ER, Weaver CM, Appel LJ. Effects of Sodium Reduction and the DASH Diet in Relation to Baseline Blood Pressure. J Am Coll Cardiol. 2017 Dec 12;70(23):2841–2848.

38. Filippini T, Malavolti M, Whelton PK, Naska A, Orsini N, Vinceti M. Blood Pressure Effects of Sodium Reduction: Dose-Response Meta-Analysis of Experimental Studies. Circulation. 2021 Apr 20;143(16):1542–1567.

39. van der Graaf AM, Paauw ND, Toering TJ, Feelisch M, Faas MM, Sutton TR, et al. Impaired sodium-dependent adaptation of arterial stiffness in formerly preeclamptic women: the RETAP-vascular study. Am J Physiol Heart Circ Physiol. 2016 Jun 1;310(11):H1827–33.

40. Young B, Hacker MR, Rana S. Physicians' knowledge of future vascular disease in women with preeclampsia. Hypertens Pregnancy. 2012;31(1):50–58.

Hosted file

`Tables final 3-23-22.docx` available at https://authorea.com/users/478781/articles/566872-postpartum-home-blood-pressure-monitoring-and-lifestyle-intervention-in-the-first-year-after-a-hypertensive-disorder-of-pregnancy-a-pilot-feasibility-trial